General

Guideline Title

ACR Appropriateness Criteria® evaluation of the symptomatic male breast.

Bibliographic Source(s)

Mainiero MB, Lourenco AP, Barke LD, Argus AD, Bailey L, Carkaci S, D'Orsi C, Green ED, Holley SO, Jokich PM, Lee SJ, Mahoney MC, Moy L, Slanetz PJ, Trikha S, Yepes MM, Newell MS, Expert Panel on Breast Imaging. ACR Appropriateness CriteriaÂ® evaluation of the symptomatic male breast [online publication]. Reston (VA): American College of Radiology (ACR); 2014. 6 p. [18 references]

Guideline Status

This is the current release of the guideline.

This guideline meets NGC's 2013 (revised) inclusion criteria.

Recommendations

Major Recommendations

ACR Appropriateness Criteria®

Clinical Condition: Evaluation of the Symptomatic Male Breast

Variant 1: Male patient of any age with symptoms of gynecomastia and physical examination consistent with gynecomastia or pseudogynecomastia.

Radiologic Procedure	Rating	Comments	RRL*
Mammography diagnostic	2		☢☢
US breast	2		O
MRI breast without and with contrast	1		O
MRI breast without contrast	1		O
Rating Scale: 1,2,3 Usually not appropriate; 4,5,6 May be appropriate; 7,8,9 Usually appropriate			***Relative Radiation Level**

Note: Abbreviations used in the tables are listed at the end of the "Major Recommendations" field.

Variant 2: Male <25 years old with indeterminate palpable breast mass. Initial examination.

Radiologic Procedure	Rating	Comments	RRL*
US breast	8		O
Mammography diagnostic	5	This procedure may be appropriate, but there was disagreement among panel members on the appropriateness rating as defined by the panel's median rating. Mammography may be indicated if US does not answer the clinical question.	☢☢
MRI breast without and with contrast	1		O
MRI breast without contrast	1		O
Rating Scale: 1,2,3 Usually not appropriate; 4,5,6 May be appropriate; 7,8,9 Usually appropriate			***Relative Radiation Level**

Note: Abbreviations used in the tables are listed at the end of the "Major Recommendations" field.

Variant 3: Male ≥25 years old with indeterminate palpable breast mass. Initial examination.

Radiologic Procedure	Rating	Comments	RRL*
Mammography diagnostic	8		☢☢
US breast	5	This procedure may be appropriate, but there was disagreement among panel members on the appropriateness rating as defined by the panel's median rating. This procedure may be indicated as the initial imaging examination if the mass is not suspected to be either gynecomastia or breast cancer (e.g., superficial soft-tissue mass far from nipple).	O
MRI breast without and with contrast	1		O
MRI breast without contrast	1		O
Rating Scale: 1,2,3 Usually not appropriate; 4,5,6 May be appropriate; 7,8,9 Usually appropriate			***Relative Radiation Level**

Note: Abbreviations used in the tables are listed at the end of the "Major Recommendations" field.

Variant 4: Male ≥25 years old with indeterminate palpable breast mass. Mammography indeterminate or suspicious.

Radiologic Procedure	Rating	Comments	RRL*
US breast	9		O
MRI breast without and with contrast	2		O
MRI breast without contrast	1		O
Rating Scale: 1,2,3 Usually not appropriate; 4,5,6 May be appropriate; 7,8,9 Usually appropriate			***Relative Radiation Level**

Note: Abbreviations used in the tables are listed at the end of the "Major Recommendations" field.

Variant 5: Male with physical examination suspicious for breast cancer (suspicious palpable breast mass, axillary adenopathy, nipple discharge, or nipple retraction).

Radiologic Procedure	Rating	Comments	RRL*
Mammography diagnostic	9		☢☢
US breast	8	US is complementary to mammography when clinical suspicion is high and when assessing extent of disease.	O
MRI breast without and with contrast	3		O
MRI breast without contrast	1		O
Rating Scale: 1,2,3 Usually not appropriate; 4,5,6 May be appropriate; 7,8,9 Usually appropriate			***Relative Radiation Level**

Summary of Literature Review

Introduction/Background

Men with breast symptoms are typically concerned about the cause of their problem and whether or not it is due to breast cancer. The majority of male breast problems are benign, with gynecomastia as the most common cause of a palpable mass, breast enlargement, or pain. Gynecomastia occurs physiologically in neonates and adolescents and with aging but can occur at any age as a side effect of many medications and illicit drugs, as a result of hormonal changes, and in the setting of chronic liver disease. Patients presenting with clinical symptoms of gynecomastia are typically younger than men with breast cancer. Breast cancer in males is rare, accounting for <1% of all breast cancers. As gynecomastia is a common physiologic change, gynecomastia and breast cancer may co-exist 50% of the time. However, gynecomastia is not believed to be a risk factor for male breast cancer. Although gynecomastia and breast cancer are the main considerations in most men with a palpable mass, other masses arising from the skin and subcutaneous tissues, such as lipomas, epidermal inclusion cysts, and oil cysts are also commonly encountered. Pseudogynecomastia, due to excess fatty tissue deposition in the breasts, is also common, especially in overweight and obese patients.

If the differentiation between benign disease and breast cancer cannot be made on the basis of clinical findings, or if the clinical presentation is suspicious, imaging is indicated.

Overview of Imaging Modalities

Mammography

Diagnostic mammography is useful in distinguishing benign breast conditions such as gynecomastia from malignancy in symptomatic males. A bilateral mammogram is routinely performed in symptomatic males, although there is no literature comparing the efficacy of bilateral versus unilateral imaging. A bilateral examination may be useful to assess for symmetry and may detect asymptomatic contralateral gynecomastia or the rare nonpalpable contralateral carcinoma.

The sensitivity and specificity of mammography for distinguishing malignant from benign breast disease in men is consistently high. A group of authors, in a series of 100 patients, reported a sensitivity of 92%, a specificity of 90%, and a negative predictive value (NPV) of 99%. Another group, in a series of 166 patients, reported a sensitivity of 100%, a specificity of 90%, and a NPV of 100%. An additional study, in a series of 638 patients, reported a sensitivity of 95%, a specificity of 95% and a NPV of 99.7%. Thus, mammography is useful both in identifying breast cancer and for obviating the need for biopsy in patients for whom the benign mammographic appearance confirms the clinical impression. Three patterns of gynecomastia have been described on mammography: nodular (subareolar nodule), dendritic (subareolar flame-shaped tissue), and diffuse glandular (much like a heterogeneously dense female breast). Breast cancer in men typically presents with an irregular mass but may present as a circumscribed mass or only with calcifications. As men do not have the same background of benign proliferative changes as do women, relatively benign imaging findings such as a circumscribed or cystic mass or punctuate calcifications should be considered suspicious in male patients.

Ultrasound

Results for breast ultrasound (US) in men are more variable. Researchers, in the series of 638 patients, reported a lower sensitivity of US for distinguishing benign from malignant disease (88.9% compared to 95% for mammography) but a similar, high specificity of 95.3%. However, another group, in their series of 166 patients, reported US to have the same sensitivity as mammography (100%) but a lower specificity of 74%. Gynecomastia often appears as a mass on US. Comparison with the contralateral side is often helpful on realtime imaging, as synchronous bilateral breast carcinoma in males is rare. One study evaluated the incremental clinical value of US in 327 symptomatic male patients where mammography was negative or revealed only gynecomastia and found no additional malignancies. However, in that series, US did lead to additional unnecessary benign biopsies. When mammography reveals questionable or suspicious findings, US can assist in clinical management and guide biopsy.

Magnetic Resonance Imaging

Data on the use of magnetic resonance imaging (MRI) in evaluation of male breast disease are limited. One study of 17 male patients investigated whether the descriptors of lesions' features and diagnostic criteria used in female patients may be used for male patients but did not assess the diagnostic accuracy or clinical usefulness of MRI in male patients.

Discussion of the Imaging Modalities by Variant

The patient's age and the level of clinical suspicion regarding the patient's symptoms and physical examination are the main determinants of what, if any, imaging is indicated.

Variant 1: Male Patient of Any Age with Symptoms of Gynecomastia and Physical Examination Consistent with Gynecomastia or Pseudogynecomastia

Most men with breast symptoms can be diagnosed on the basis of clinical findings without imaging. Gynecomastia is bilateral in approximately half of patients. On physical examination, gynecomastia often presents as a soft, rubbery, or firm mobile mass directly under the nipple. In addition, gynecomastia is more likely to be painful than cancer, especially gynecomastia that has been present for <6 months.

Variant 2: Male <25 Years Old with Indeterminate Palpable Breast Mass; Initial Examination

Breast cancer is a disease of older men and typically presents at a later age than in women, at a median age of 63 years. Only 6% of male breast cancers occur under the age of 40 and 1% under the age of 30. Because of the relationship of breast cancer to increasing age, age-based protocols that do not include mammography in younger men have been developed. Some authors suggest using US is useful as the initial imaging modality in the young male who is unlikely to have breast cancer and who presents with an indeterminate physical symptom. However, gynecomastia and oil cysts can have a suspicious appearance on US but can typically be diagnosed as benign on mammography. Therefore, if there are suspicious features on US, mammography should be performed before a biopsy recommendation is made.

Variants 3 and 4: Male ≥25 Years Old with Indeterminate Palpable Breast Mass; Initial Examination and Next Examination if Mammography is Indeterminate or Suspicious

For men with an equivocal physical examination and of an age at which breast cancer is more likely, mammography is recommended as the initial imaging modality. Mammography is highly sensitive and specific in distinguishing benign from malignant disease and is likely more sensitive than US at detecting breast cancer due to the ability to visualize microcalcifications. When mammography is diagnostic of gynecomastia, US is not typically necessary. US can be used as an adjunct to mammography if the mammogram is indeterminate or suspicious or if mammography does not reveal a cause for the palpable finding.

Variant 5: Male with Physical Examination Suspicious for Breast Cancer (Suspicious Palpable Breast Mass, Nipple Discharge, or Nipple Retraction)

Male breast cancer usually presents quite differently than gynecomastia. Male breast cancer is rarely bilateral and typically presents with a painless, hard, subareolar mass, often eccentric to the nipple. With breast cancer, there may be secondary signs of malignancy such as nipple or skin retraction, nipple discharge, or axillary lymphadenopathy.

Breast cancers in men often present at a more advanced stage than breast cancers in women, with up to 47% of men having axillary nodal involvement at the time of diagnosis. In addition, nipple discharge is suspicious for breast cancer in men, with 2 studies showing carcinoma in 23% to 57% of men presenting with this symptom.

For men with a highly suspicious physical finding, mammography is recommended as the initial imaging study with US useful in assisting with clinical management decisions and in guidance for biopsy.

Summary of Recommendations

- Men with typical symptoms of gynecomastia or pseudogynecomastia do not usually need imaging.
- For men with an indeterminate palpable mass, begin with US if the patient is <25 years of age, as breast cancer is highly unlikely. Mammography should be performed if US is suspicious.
- For men ≥25 years of age, or men with a highly concerning physical examination, begin with mammography. US is useful if mammography is inconclusive or suspicious.

Abbreviations

- MRI, magnetic resonance imaging
- US, ultrasound

Relative Radiation Level Designations

Relative Radiation Level*	Adult Effective Dose Estimate Range	Pediatric Effective Dose Estimate Range
O	0 mSv	0 mSv
☢	<0.1 mSv	<0.03 mSv
☢☢	0.1-1 mSv	0.03-0.3 mSv
☢☢☢	1-10 mSv	0.3-3 mSv
☢☢☢☢	10-30 mSv	3-10 mSv
☢☢☢☢☢	30-100 mSv	10-30 mSv
*RRL assignments for some of the examinations cannot be made, because the actual patient doses in these procedures vary as a function of a number of factors (e.g., region of the body exposed to ionizing radiation, the imaging guidance that is used). The RRLs for these examinations are designated as "Varies."		

Clinical Algorithm(s)

Algorithms were not developed from criteria guidelines.

Scope

Disease/Condition(s)

Symptomatic male breast

Guideline Category

Diagnosis

Evaluation

Clinical Specialty

Family Practice

Internal Medicine

Radiology

Intended Users

Allied Health Personnel

Health Plans

Hospitals

Managed Care Organizations

Physicians

Utilization Management

Guideline Objective(s)

To evaluate the appropriateness of imaging modalities for the assessment of male patients with breast symptoms

Target Population

Male patients with breast symptoms

Interventions and Practices Considered

1. Mammography diagnostic
2. Ultrasound (US), breast
3. Magnetic resonance imaging (MRI), breast
    - Without and with contrast
    - Without contrast

Major Outcomes Considered

- Utility of radiologic examinations in evaluation of the symptomatic male breast
- Sensitivity and specificity of radiologic examinations
- Positive and negative predictive values of radiologic examinations

Methodology

Methods Used to Collect/Select the Evidence

Hand-searches of Published Literature (Primary Sources)

Hand-searches of Published Literature (Secondary Sources)

Searches of Electronic Databases

Description of Methods Used to Collect/Select the Evidence

Literature Search Summary

A literature search was conducted in July 2013 to identify evidence for the *ACR Appropriateness Criteria® Evaluation of the Symptomatic Male Breast* topic. Using the search strategy described in the literature search companion (see the "Availability of Companion Documents" field), 64 articles were found. Six articles were used in the topic. Fifty-eight articles were not used due to either poor study design, the articles were not relevant or generalizable to the topic, or the results were unclear, misinterpreted, or biased.

The author added 12 citations from bibliographies, websites, or books that were not found in the literature search.

See also the American College of Radiology (ACR) Appropriateness Criteria® literature search process document (see the "Availability of Companion Documents" field) for further information.

Number of Source Documents

Six articles were used in the topic. The author added 12 citations from bibliographies, Web sites, or books that were not found in the literature

search.

Methods Used to Assess the Quality and Strength of the Evidence

Weighting According to a Rating Scheme (Scheme Given)

Rating Scheme for the Strength of the Evidence

Study Quality Category Definitions

Category 1 - The study is well-designed and accounts for common biases.

Category 2 - The study is moderately well-designed and accounts for most common biases.

Category 3 - There are important study design limitations.

Category 4 - The study is not useful as primary evidence. The article may not be a clinical study or the study design is invalid, or conclusions are based on expert consensus. For example:

a. The study does not meet the criteria for or is not a hypothesis-based clinical study (e.g., a book chapter or case report or case series description).
b. The study may synthesize and draw conclusions about several studies such as a literature review article or book chapter but is not primary evidence.
c. The study is an expert opinion or consensus document.

Methods Used to Analyze the Evidence

Systematic Review with Evidence Tables

Description of the Methods Used to Analyze the Evidence

The topic author assesses the literature then drafts or revises the narrative summarizing the evidence found in the literature. American College of Radiology (ACR) staff drafts an evidence table based on the analysis of the selected literature. These tables rate the study quality for each article included in the narrative.

The expert panel reviews the narrative, evidence table and the supporting literature for each of the topic-variant combinations and assigns an appropriateness rating for each procedure listed in the variant table(s). Each individual panel member assigns a rating based on his/her interpretation of the available evidence.

More information about the evidence table development process can be found in the ACR Appropriateness Criteria® Evidence Table Development document (see the "Availability of Companion Documents" field).

Methods Used to Formulate the Recommendations

Expert Consensus (Delphi)

Description of Methods Used to Formulate the Recommendations

Rating Appropriateness

The American College of Radiology (ACR) Appropriateness Criteria (AC) methodology is based on the RAND Appropriateness Method. The appropriateness ratings for each of the procedures or treatments included in the AC topics are determined using a modified Delphi method. A series of surveys are conducted to elicit each panelist's expert interpretation of the evidence, based on the available data, regarding the appropriateness of an imaging or therapeutic procedure for a specific clinical scenario. The expert panel members review the evidence presented

and assess the risks or harms of doing the procedure balanced with the benefits of performing the procedure. The direct or indirect costs of a procedure are not considered as a risk or harm when determining appropriateness. When the evidence for a specific topic and variant is uncertain or incomplete, expert opinion may supplement the available evidence or may be the sole source for assessing the appropriateness.

The appropriateness is represented on an ordinal scale that uses integers from 1 to 9 grouped into three categories: 1, 2, or 3 are in the category "usually not appropriate" where the harms of doing the procedure outweigh the benefits; and 7, 8, or 9 are in the category "usually appropriate" where the benefits of doing a procedure outweigh the harms or risks. The middle category, designated "may be appropriate," is represented by 4, 5, or 6 on the scale. The middle category is when the risks and benefits are equivocal or unclear, the dispersion of the individual ratings from the group median rating is too large (i.e., disagreement), the evidence is contradictory or unclear, or there are special circumstances or subpopulations which could influence the risks or benefits that are embedded in the variant.

The ratings assigned by each panel member are presented in a table displaying the frequency distribution of the ratings without identifying which members provided any particular rating. To determine the panel's recommendation, the rating category that contains the median group rating without disagreement is selected. This may be determined after either the first or second rating round. If there is disagreement after the second rating round, the recommendation is "May be appropriate."

This modified Delphi method enables each panelist to articulate his or her individual interpretations of the evidence or expert opinion without excessive influence from fellow panelists in a simple, standardized and economical process. For additional information on the ratings process see the Rating Round Information document on the ACR Web site.

Additional methodology documents, including a more detailed explanation of the complete topic development process and all ACR AC topics can be found on the ACR Web site (see also the "Availability of Companion Documents" field).

Rating Scheme for the Strength of the Recommendations

Not applicable

Cost Analysis

A formal cost analysis was not performed and published cost analyses were not reviewed.

Method of Guideline Validation

Internal Peer Review

Description of Method of Guideline Validation

Criteria developed by the Expert Panels are reviewed by the American College of Radiology (ACR) Committee on Appropriateness Criteria.

Evidence Supporting the Recommendations

Type of Evidence Supporting the Recommendations

The recommendations are based on analysis of the current literature and expert panel consensus.

Summary of Evidence

Of the 18 references cited in the *ACR Appropriateness Criteria® Evaluation of the Symptomatic Male Breast* document, 1 is categorized as a good quality therapeutic study. Additionally, 16 references are categorized as diagnostic references including 1 good quality study and 7 quality studies that may have design limitations. There are 9 references that may not be useful as primary evidence.

While there are references that report on studies with design limitations, two good quality studies provide good evidence.

Benefits/Harms of Implementing the Guideline Recommendations

Potential Benefits

Selection of appropriate radiologic imaging procedures for evaluation of the symptomatic male breast

Potential Harms

Gadolinium-based Contrast Agents

Nephrogenic systemic fibrosis (NSF) is a disorder with a scleroderma-like presentation and a spectrum of manifestations that can range from limited clinical sequelae to fatality. It appears to be related to both underlying severe renal dysfunction and the administration of gadolinium-based contrast agents. It has occurred primarily in patients on dialysis, rarely in patients with very limited glomerular filtration rate (GFR) (i.e., <30 mL/min/1.73 m^2), and almost never in other patients. Although some controversy and lack of clarity remain, there is a consensus that it is advisable to avoid all gadolinium-based contrast agents in dialysis-dependent patients unless the possible benefits clearly outweigh the risk, and to limit the type and amount in patients with estimated GFR rates <30 mL/min/1.73 m^2. For more information, please see the American College of Radiology (ACR) Manual on Contrast Media (see the "Availability of Companion Documents" field).

Relative Radiation Level

Potential adverse health effects associated with radiation exposure are an important factor to consider when selecting the appropriate imaging procedure. Because there is a wide range of radiation exposures associated with different diagnostic procedures, a relative radiation level (RRL) indication has been included for each imaging examination. The RRLs are based on effective dose, which is a radiation dose quantity that is used to estimate population total radiation risk associated with an imaging procedure. Patients in the pediatric age group are at inherently higher risk from exposure, both because of organ sensitivity and longer life expectancy (relevant to the long latency that appears to accompany radiation exposure). For these reasons, the RRL dose estimate ranges for pediatric examinations are lower as compared to those specified for adults. Additional information regarding radiation dose assessment for imaging examinations can be found in the ACR Appropriateness Criteria® Radiation Dose Assessment Introduction document (see the "Availability of Companion Documents" field).

Qualifying Statements

Qualifying Statements

The American College of Radiology (ACR) Committee on Appropriateness Criteria and its expert panels have developed criteria for determining appropriate imaging examinations for diagnosis and treatment of specified medical condition(s). These criteria are intended to guide radiologists, radiation oncologists, and referring physicians in making decisions regarding radiologic imaging and treatment. Generally, the complexity and severity of a patient's clinical condition should dictate the selection of appropriate imaging procedures or treatments. Only those examinations generally used for evaluation of the patient's condition are ranked. Other imaging studies necessary to evaluate other co-existent diseases or other medical consequences of this condition are not considered in this document. The availability of equipment or personnel may influence the selection of appropriate imaging procedures or treatments. Imaging techniques classified as investigational by the U.S. Food and Drug Administration (FDA) have not been considered in developing these criteria; however, study of new equipment and applications should be encouraged. The ultimate decision regarding the appropriateness of any specific radiologic examination or treatment must be made by the referring physician and radiologist in light of all the circumstances presented in an individual examination.

Implementation of the Guideline

Description of Implementation Strategy

An implementation strategy was not provided.

Institute of Medicine (IOM) National Healthcare Quality Report Categories

IOM Care Need

Getting Better

Staying Healthy

IOM Domain

Effectiveness

Identifying Information and Availability

Bibliographic Source(s)

Mainiero MB, Lourenco AP, Barke LD, Argus AD, Bailey L, Carkaci S, D'Orsi C, Green ED, Holley SO, Jokich PM, Lee SJ, Mahoney MC, Moy L, Slanetz PJ, Trikha S, Yepes MM, Newell MS, Expert Panel on Breast Imaging. ACR Appropriateness CriteriaÂ® evaluation of the symptomatic male breast [online publication]. Reston (VA): American College of Radiology (ACR); 2014. 6 p. [18 references]

Adaptation

Not applicable: The guideline was not adapted from another source.

Date Released

2014

Guideline Developer(s)

American College of Radiology - Medical Specialty Society

Source(s) of Funding

The American College of Radiology (ACR) provided the funding and the resources for these ACR Appropriateness Criteria®.

Guideline Committee

Committee on Appropriateness Criteria, Expert Panel on Breast Imaging

Composition of Group That Authored the Guideline

Panel Members: Martha B. Mainiero, MD (*Principal Author*); Ana P. Lourenco, MD (*Co-author*); Lora D. Barke, DO (*Panel Vice-chair*); Amy D. Argus, MD; Lisa Bailey, MD; Selin Carkaci, MD; Carl D'Orsi, MD; Edward D. Green, MD; Susan O. Holley, MD; Peter M. Jokich, MD; Su-Ju Lee, MD; Mary C. Mahoney, MD; Linda Moy, MD; Priscilla J. Slanetz, MD, MPH; Sunita Trikha, MD; Monica M. Yepes, MD;

Mary S. Newell, MD (*Panel Chair*)

Financial Disclosures/Conflicts of Interest

Not stated

Guideline Status

This is the current release of the guideline.

This guideline meets NGC's 2013 (revised) inclusion criteria.

Guideline Availability

Electronic copies: Available from the American College of Radiology (ACR) Web site .

Print copies: Available from the American College of Radiology, 1891 Preston White Drive, Reston, VA 20191. Telephone: (703) 648-8900.

Availability of Companion Documents

The following are available:

- ACR Appropriateness Criteria®. Overview. Reston (VA): American College of Radiology; 2015 Feb. 3 p. Electronic copies: Available from the American College of Radiology (ACR) Web site .
- ACR Appropriateness Criteria®. Literature search process. Reston (VA): American College of Radiology; 2015 Feb.1 p. Electronic copies: Available from the ACR Web site .
- ACR Appropriateness Criteria®. Evidence table development – diagnostic studies. Reston (VA): American College of Radiology; 2013 Nov. 3 p. Electronic copies: Available from the ACR Web site .
- ACR Appropriateness Criteria®. Radiation dose assessment introduction. Reston (VA): American College of Radiology; 2015 Feb. 3 p. Electronic copies: Available from the ACR Web site .
- ACR Appropriateness Criteria®. Procedure information. Reston (VA): American College of Radiology; 2015 Feb; 2 p. Electronic copies: Available from the ACR Web site .
- ACR Appropriateness Criteria® Manual on contrast media. Reston (VA): American College of Radiology; 2013. 128 p. Electronic copies: Available from the ACR Web site .
- Appropriateness Criteria® evaluation of the symptomatic male breast. Evidence table. American College of Radiology; 2014. 9 p. Electronic copies: Available from the ACR Web site .
- Appropriateness Criteria® evaluation of the symptomatic male breast. Literature search. American College of Radiology; 2014. 1 p. Electronic copies: Available from the ACR Web site .

Patient Resources

None available

NGC Status

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